

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS**

JOSH COOK, individually and on behalf of
those similarly situated,

Plaintiff,

v.

COLGATE-PALMOLIVE COMPANY,
individually and as successor-in-interest to
HELLO PRODUCTS LLC,

Defendant.

Case No. 1:25-cv-05448

AMENDED CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Josh Cook, by his undersigned counsel, on behalf of himself and all persons similarly situated who purchased Hello “Kids Fluoride Rinse” for their preschool children, brings this class action lawsuit against defendant Colgate-Palmolive Company, individually and as successor-in-interest to Hello Products LLC (“**Defendant**”). Plaintiff alleges the following upon information and belief, except for those allegations that pertain to Plaintiff, which are based on Plaintiff’s personal knowledge.

INTRODUCTION

1. Defendant manufactures and sells a “naturally friendly” fluoride mouthrinse that it specifically markets for use by kids called Hello Kids Fluoride Rinse (“**Hello Rinse**” or “**Rinse**”). The Rinse comes in two kid-enticing flavors: Wild Strawberry and Bubble Gum.

2. The label of Defendant’s Wild Strawberry Rinse states it is “thoughtfully formulated with wild strawberry natural flavor and xylitol” and “tastes so delicious they’ll rush to rinse.”

3. The label of Defendant’s Bubble Gum Rinse describes the candy-flavored liquid as a “unicorn splash” that “tastes magical” and “tastes like rainbows and sunshine (aka bubble gum).”



4. In addition to showcasing its “delicious” and “magical” flavors, the Hello Rinse label boasts that the liquid does not contain harmful or unhealthy ingredients: “vegan. no alcohol. no dyes. no artificial flavors. no SLS/sulfates. no brainer.”

5. While Defendant’s labeling conveys the impression that the rinse is specially formulated to be *safe* for young children, it is not. The reality is that fluoride mouthrinse is considered by the U.S. Food and Drug Administration (“**FDA**”) to be too dangerous for children under 6 to use.

6. Hello Rinse, which has the same fluoride concentration as adult rinses, is actually *more* dangerous for young children than adult rinses because it comes in candy and fruit flavors that entice children to use and swallow more of the product.

7. As far back as 1960, it was known that fluoride mouthrinses “should not be employed in children below school age.”¹

8. The FDA states that fluoride mouthrinses “are not indicated for use in children under 6 years of age on an [over-the-counter] basis” and “should not be within easy reach of any children.”²

9. The American Dental Association (“ADA”) states that “Children younger than the age of 6 should not use mouthrinse, unless directed by a dentist, because they may swallow large amounts of the liquid inadvertently.”³

10. The World Health Organization (“WHO”) states that fluoride mouthrinses “are not recommended for children below the age of 6 years.”⁴

11. The American Academy of Pediatrics (“AAP”) states that fluoride mouth rinses should not be used until a child turns 6 and, even then, only “if the child can reliably swish and spit” and is at high risk of tooth decay.⁵

12. The U.S. Centers for Disease Control and Prevention (“CDC”) states that “children

¹ Ingrid Hellstrom, *Fluoride retention following sodium fluoride mouthwashing*, 18 ACTA ODONTOL SCAND. 263, 273 (1960).

² FDA, *Anticaries Drug Products for Over-the-Counter Human Use; Final Monograph*, 60 Fed. Reg. 52474, 52486 (Oct. 6, 1995).

³ ADA, *Mouthrinse (Mouthwash) – Key Points*, <https://www.ada.org/resources/ada-library/oral-health-topics/mouthrinse-mouthwash>.

⁴ WORLD HEALTH ORGANIZATION. FLUORIDES AND ORAL HEALTH 33 (1994).

⁵ Melinda B. Clark, et al., *Fluoride Use in Caries Prevention in the Primary Care Setting*, 146 PEDIATRICS e2020034637, Tbl 1 (2020).

aged <6 years should not use fluoride mouthrinse without consultation with a dentist or other health-care provider.”⁶

13. According to Defendant, “babies and toddlers should not use [fluoride] mouthrinse” because “children under six may not have fully developed their swallowing reflexes and could swallow the mouthrinse,” which can “lead to side effects like vomiting, intoxication, and nausea.”⁷

14. Despite the scientific consensus that fluoride mouthrinses are contraindicated for children under six years of age, Defendant targets this age group with its Hello Rinse.

15. In its efforts to appeal to young children, Defendant presents fluoride mouthrinse (a drug that should *not* be swallowed by any age group, especially young children) as a juice-like and candy-like product. This is both deceptive and dangerous.

16. It is well recognized that presenting drugs as candy- and fruit-like products increases the risk of overdose, particularly for young children. In 1997, the *Journal of Public Health Dentistry* published a review, stating “The use of flavored consumer fluoride products increases the possibility that a child will ingest a toxic dose of fluoride.”⁸ A more recent review in the *Journal of Dental Hygiene* warned that boasting “pictures of fruit with flavoring to match” on kids fluoride products is “misleading” because pictures of fruit send a “common signal” that the product “is intended to be consumed as if it were food.”⁹

⁶ CDC, *Recommendations for using fluoride to prevent and control dental caries in the United States*. Centers for Disease Control and Prevention, 50 MMWR RECOMM REP. 1, 26 (2001).

⁷ Colgate, *What Parents Should Know About Mouthwash for Children*, <https://www.colgate.com/en-us/oral-health/kids-oral-care/what-parents-should-know-about-mouthwash-for-children> (last accessed Jan. 13, 2025).

⁸ Jay D. Shulman & Linda M. Wells, *Acute fluoride toxicity from ingesting home-use dental products in children, birth to 6 years of age*, 57 J PUBLIC HEALTH DENT. 150, 150 (1997).

⁹ Corey H. Basch & Sonali Rajan, *Marketing strategies and warning labels on children's*

17. Swallowing excessive amounts of fluoride is hazardous to health.

18. Hello Rinse has enough fluoride in it to kill a small child. A toddler who ingests just over half of the sweet flavored liquid in the bottle may suffer severe poisoning, including death. See *infra* ¶¶ 75-78.

19. The risk of toxicity is not limited to those children who intentionally drink the product. Even small amounts of the rinse can cause symptoms of acute toxicity if ingested.

20. A single 10 mL dose of Hello Rinse contains 2.3 milligrams of fluoride. A toddler who swallows this 10 mL dose can suffer nausea, vomiting, and other early symptoms of acute fluoride toxicity. See *infra* ¶¶ 67-74.

21. There are thousands of poison control reports for excess ingestion of fluoride mouthrinse by young children each year. But these reports represent only a fraction of the total number of incidents. See *infra* ¶¶ 79-82.

22. Another problem with young children using fluoride mouthrinse is that it can cause dental fluorosis.¹⁰ Fluorosis is a defect of tooth enamel that is marked by “increased porosity” and “less than normal amounts of calcification in the teeth.”¹¹ This defect causes visible, and sometimes disfiguring, staining of the enamel. See *infra* ¶¶ 64-66.

23. The FDA recognizes that preschool children who use fluoride mouthrinse are at risk of developing dental fluorosis, but did not require a fluorosis warning *because children under*

toothpaste, 88 J DENT HYG. 316, 316 (2014).

¹⁰ CDC, *About Fluoride*, <https://www.cdc.gov/oral-health/prevention/about-fluoride.html> (“If children repeatedly swallow mouth rinses, they may develop dental fluorosis.”).

¹¹ NATIONAL RESEARCH COUNCIL, FLUORIDE IN DRINKING WATER: A SCIENTIFIC REVIEW OF EPA’S STANDARDS 104 (2006); Crest, *Dental Fluorosis: Causes, Treatments & Prevention*, <https://crest.com/en-us/oral-care-tips/tooth-enamel/dental-fluorosis-causes-treatments-prevention> (last accessed Jan. 13, 2025).

six are not supposed to be using the product. To quote: “Because fluoride dental rinses and gels are recommended only for use in adults and children 6 years of age and older, the agency believes that a warning about discoloration of developing teeth in children under 6 years of age is not needed on an OTC market package.”¹²

24. The health risks of preschool children using fluoride mouthrinse are of such magnitude that scientists have never even attempted to study the potential effect of fluoride mouthrinses on tooth decay in this age group. Therefore, there are no demonstrated benefits from the use of fluoride mouthrinses for preschool children, particularly in the current context of widespread exposure to fluoride from toothpaste, fluoridated water, and processed foods.

25. Due to the dangers posed by fluoride in mouthrinse form, it is critical that consumers be alerted of the need to take special precautions to avoid ingesting toxic levels of fluoride.

26. By 1960, it was known that “**careful instruction . . . must be provided**” if fluoride mouthrinses are to be used on a daily basis.¹³

27. The FDA is concerned that many consumers will fail to appreciate that fluoride mouthrinses present dangers that are not present with ordinary cosmetic mouthrinses. According to the FDA, “based upon familiarity with cosmetic mouthrinse use, a consumer might overuse and/or misuse an OTC fluoride rinse.”¹⁴

28. Because many consumers will not appreciate the risks posed by fluoride mouthrinse, the FDA has stressed that the “safe” use of fluoride mouthrinse requires “proper

¹² FDA, *Anticaries Drug Products for Over-the-Counter Use; Tentative Final Monograph; Notice of Proposed Rulemaking*, 59 Fed. Reg. 39854, 39864 (Sept. 30, 1985).

¹³ Hellstrom, *supra* note 1, at 273 (emphasis added).

¹⁴ FDA, *supra* note 2, at 52485.

labeling.”¹⁵ Towards this end, the FDA specifically commands that the labeling for fluoride mouthrinses “**clearly instructs consumers to read the directions.**”¹⁶

29. In order to ensure consumers read the directions, the FDA requires sellers of fluoride mouthrinse to “**prominently**” place a notice on the **front label** of the product.¹⁷ The regulation states that “the following statement shall be prominently placed on the principal display panel: ‘IMPORTANT: Read directions for proper use.’” 21 C.F.R. § 355.55.

30. Defendant is flagrantly violating this regulation as it does not provide this notice anywhere on the Hello Rinse, let alone in a prominent way on the front label.

31. Defendant is well aware that Hello Rinse is popular among preschool children and their caregivers. The following are examples of customer reviews that were readily available on the Defendant’s own website as of January of this year¹⁸:

- a. “I was given this product to try as part of the weeSpring Parent Panel. We tried the strawberry flavor mouthwash and, as predicted, my kids loved it. My young children (6 yr, **4 yr and 2 yr**) looked forward to using it every day after brushing. It tastes good, they like to keep it in their mouth for the requisite rinse time.”
- b. “My only complaint would be they find a better way to measure the amounts in a spill proof way (my **3 year-old** proof essentially)”
- c. “Toothbrushing time is already a not fun time in our household when you have

¹⁵ *Id.*

¹⁶ *Id.* (emphasis added).

¹⁷ *Id.*

¹⁸ <https://www.hello-products.com/products/kids-fluoride-strawberry-mouthwash> (last accessed Jan. 13, 2025). This link, which was active when Mr. Cook filed a lawsuit against Defendant on January 13, 2025 in the Southern District of California, has since been removed from the internet.

a **5 and 3 year old!** This is their first time using a mouthwash and they really enjoyed the experience and flavor of it! It helps to keep their breath fresh, teeth cavity free, and mommy happy!”

- d. “My **4 year old** son actually looks forward to using mouthwash. It used to just be another step in the routine but he gets so excited! After he spits it out, he says ‘Yummmm!’. Having tried it out myself before him, I’d have to agree! We love that it’s natural and effective. What we put in our kiddos bodies is SO important!”
- e. “We are realllllly enjoying this strawberry rinse from Hello Kids--especially my **4y/o.**”
- f. “Kids aren't supposed to get excited about dental hygiene, are they? Apparently I was wrong. My **4 year old** son's new favorite treat is Hello Wild Strawberry Rinse.”
- g. “I’ve got a 6 year old and **almost 4 year old** and they both loved the wild strawberry flavor so much that and would remind me to open the mouth rinse if I forgot. I would recommend this to other parents. Definitely buying this again!”
- h. “My daughter is **four and a half**, and doesn't brush her teeth very thoroughly, even with my assistance. . . . My daughter loves the taste, and actually looks forward to using it every day. It’s now her favorite flavor of fluoride rinse, and I plan on buying this for her whenever she runs out of it.
- i. “My **5 year old** looooves the flavor. He asks to use it all the time:)”
- j. “My **5 year old** loves using this rinse.”

- k. “After receiving the mouthwash from weeSpring Parent Panel, we have concluded we love Hello Kids Flouride Rinse! My **5 year old** asks every night now if he can swish. Why? Because this rinse is a delicious strawberry flavor, making it so kid friendly! It's also mom approved, since it's so natural.”
- l. “My **5 year old** has sensory processing disorder so I was a little concerned on how he would handle trying a mouth rinse, what got me interested in the wild strawberry Hello kids flouride rinse was that it has no alcohol so no burning sensation. To assure him, I tried it first. Berry flavored is generally reserved for kids things but to my surprise, I liked it! When my son tried it he said, ‘Yum! It doesnt even burn my mouth!’”

32. The targeting of young children with fruit- and candy-flavored fluoride products is believed to be one of the reasons for the increase in dental fluorosis that has been observed in recent decades.¹⁹

33. Since the introduction of fruit- and candy-like fluoride products in the 1980s, the rate of dental fluorosis among U.S. schoolchildren has skyrocketed. In 1986-87, approximately 23% of U.S. children had fluorosis.²⁰ This rate tripled to a staggering 68% of U.S children by 2015-16.²¹

34. With millions of U.S. children showing visible signs of excess fluoride exposure, there is growing concern about other chronic health conditions that fluoride may be causing,

¹⁹ Christopher Neurath, et al., *Dental Fluorosis Trends in US Oral Health Surveys: 1986 to 2012*, 4 JDR CLIN TRANS RES. 298, 306 (2019).

²⁰ Keith E. Heller, *Dental caries and dental fluorosis at varying water fluoride concentrations*, 57 J PUBLIC HEALTH DENT. 136, 139 Tbl 5 (1997).

²¹ Man Hung et al., *A National Study Exploring the Association Between Fluoride Levels and Dental Fluorosis*, 6 JAMA NETW OPEN. e2318406 (2023).

including neurodevelopmental disorders and endocrine disruption. In August of 2024, the prestigious National Toxicology Program (NTP) concluded that excess fluoride exposure is associated with IQ loss in children, and, in September 2024, a federal district court concluded that adding fluoride to drinking water presents an unreasonable risk of reduced IQ. See *infra* ¶¶ 86-90.

35. In recognition of the growing health concerns with fluoride ingestion, the FDA announced on May 13, 2025 that it intends to remove ingestible fluoride prescription products from the market.²²

36. Plaintiff brings this action to hold Defendant accountable for its deceptive packaging of Hello Rinse, which puts the health of millions of children at risk. Defendant's deceptive packaging of Hello Rinse violates the Federal Food Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 352(a),²³ and many state consumer fraud statutes, including the Illinois Consumer Fraud and Deceptive Trade Practices Act, 815 ILCS § 505/2.

37. Plaintiff does not seek to impose any requirement that goes beyond, is not identical to, or is different from, the requirements that are imposed on Defendant under the FDCA and its accompanying regulations, including the FDA Monograph on anti-cavity drugs. See C.F.R. §§ 355.50 & 355.55. Plaintiff seeks instead to hold Defendant responsible for the elements of its products that are *not* required by the Monograph *and* which violate its obligations under both federal and state law. A judicial finding that these voluntary elements are false, misleading, and/or

²² Food & Drug Administration, *FDA Begins Action To Remove Ingestible Fluoride Prescription Drug Products for Children from the Market*, <https://www.fda.gov/news-events/press-announcements/fda-begins-action-remove-ingestible-fluoride-prescription-drug-products-children-market>.

²³ Plaintiff recognizes that there is no private right of action under FDCA and does not assert such a claim here. Instead, Plaintiff's allegations that Defendant violated the requirements of the FDCA serve as a prerequisite for the state law claims. See, e.g., *In re Beyond Meat, Inc.*, No. 23 C 669, 2024 U.S. Dist. LEXIS 30397, at *21 (N.D. Ill. Feb. 21, 2024) ("[T]o avoid preemption, a state law claim related to misleading labeling must allege a violation of the FDCA or its regulations.").

deceptive would be harmonious and not in conflict with the FDCA.²⁴

PARTIES

38. Plaintiff **Josh Cook** is, and all times relevant to this complaint has been, a citizen of Illinois.

39. Mr. Cook lives in Rockford, Illinois and has purchased Hello Rinse for his minor daughter Z.C.

40. Mr. Cook purchased Hello Rinse for Z.C. from approximately 2021 to 2023 when Z.C. was 3 to 5 years of age.

41. Mr. Cook purchased the Hello Rinse at stores in the Rockford area. He believes he purchased the products at Target and/or Meijer.

42. Mr. Cook did not purchase the Hello Rinse at the direction of a dentist, doctor, or health care provider.

43. Based on Defendant's packaging, Mr. Cook believed Hello Rinse was specially formulated to be safe for young children and would not present any risks to Z.C.

44. Z.C. enjoyed the flavor of the rinse.

45. If Mr. Cook had known that fluoride mouthrinse is contraindicated for children under 6 years of age, he would not have purchased Hello Rinse, or any other fluoride rinse.

46. Defendant **Colgate Palmolive Company** is, and at all times mentioned in this

²⁴ See, e.g., *Bell v. Publix Super Mkts., Inc.*, 982 F.3d 468, 485 (7th Cir. 2020) ("The FDCA's preemption provision means that, while states may not require sellers to add further labeling that is not required by federal law, they may prevent sellers from voluntarily adding deceptive content that is not required by federal law."); *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 758 (9th Cir. 2015) ("FDA regulations do not require Hain to label its products as 'All Natural' or 'Pure Natural.' If Astiana's suit ultimately requires Hain to remove these allegedly misleading advertising statements from its product labels, such a result does not run afoul of the FDCA, which prohibits 'requirement[s]' that are 'different from,' 'in addition to,' or 'not identical with' federal rules.").

Complaint was, a corporation incorporated in the state of Delaware with a principal place of business 300 Park Avenue, New York, NY 10022. In September 2024, Defendant acquired all of the assets and liabilities of Hello Products LLC, including the Hello Rinses at issue in this litigation. Defendant continues to manufacture and sell Hello Rinses.

JURISDICTION AND VENUE

47. This Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. §1332(d)(2) and the Class Action Fairness Act of 2005 (“CAFA”), because (i) there are 100 or more class members; (ii) there is an aggregate amount in controversy exceeding \$5,000,000, exclusive of interest and costs; and (iii) there is minimal diversity because at least one member of the class and defendant are citizens of different states. This court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.

48. The aggregate amount in controversy plausibly exceeds \$5,000,000 based on the following facts, which are based on information and belief and can be confirmed through Defendant’s records: (A) Defendant’s Hello product line has undergone an exponential increase in sales over the past 7 years, with an estimated \$76.7 million in annual U.S. sales by 2020; (B) Defendant’s Hello Rinse is the second largest selling children’s mouthwash on Amazon; (C) Defendant’s Hello Rinse is sold on the shelves of large retailers, including Walmart, Target, and Whole Foods; (C) there are approximately 2,250 Walmart and Target stores located in the jurisdictions in the proposed class, and the vast majority, if not all, of these stores sell Hello Rinse; (D) Defendant conservatively sells at least 225,000 units of Hello Rinse a year in the jurisdictions of the proposed class; (E) a majority of the Hello Rinse units are purchased for children under the age of six; (E) the average price of a single Hello Rinse unit has been approximately \$5 to \$6 during the class period, and will likely increase in the years ahead; and (F) the class period will

likely continue until 2027 or 2028, for a total of 7 to 8 years.

49. This Court has personal jurisdiction over Defendant because the injuries upon which Mr. Cook's claims are based occurred or arose out of activities that Defendant specifically engaged in within the State of Illinois. Defendant knowingly and intentionally distributed its mouthrinse products for sale in Illinois, and Plaintiff thereupon purchased Defendant's mouthrinse products from a retail store(s) located in Illinois.

50. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claims occurred in the State of Illinois, including within the Northern District.

FACTUAL ALLEGATIONS

A. Fluoride Mouthrinse Poses a Much Greater Risk to Young Children than Adults

51. For a multitude of reasons, young children are more vulnerable to suffering harm from fluoride mouthrinse than adolescents and adults.

52. Young children have poorly developed swallowing reflexes and, as a result, swallow a large percentage of the rinse that they put into their mouth, whether they want or intend to or not. This remains the case even when the child is instructed not to swallow. As the FDA has explained, "Children under 6 years of age . . . have not developed control of their swallowing reflex and are not able to hold the fluoride preparation in their mouth and then expectorate properly."²⁵

53. Between mouthrinse and toothpaste, the former poses a greater risk of excess ingestion for young children. This is because fluoride mouthrinses "do not contain an abrasive that can bind some of the fluoride ion and because a child under 6 is more likely to drink a flavored

²⁵ FDA, *supra* note 12, at 39867.

liquid than eat large amounts of toothpaste.”²⁶

54. The lack of a developed swallowing reflex is particularly acute for children under the age of three. In a study designed to estimate exposure from fluoride mouthrinse, “most 2 year old children and some 3 year old children could not perform mouthrinsing with water, but instead quickly swallowed the fluid.”^{27,28}

55. According to the CDC, “studies of the amount of fluoride swallowed by children aged 3-5 years using such rinses indicated that some young children might swallow substantial amounts.”²⁹

56. Even when ingesting the same amount of mouthrinse as an adult, young children receive a far higher fluoride dose by bodyweight (mg/kg/day) due to their smaller body size.

57. A 2 year old child of average weight (~12 kg) who ingests a single dose of Hello Rinse³⁰ will ingest 0.19 mg/kg of fluoride, which is more than two times higher than EPA’s reference dose (0.08 mg/kg/day) for fluoride. According to EPA, children who ingest more than 0.08 mg/kg/day are at risk of developing “*severe* dental fluorosis.”³¹

B. Ingesting Fluoride Mouthrinse During Early Childhood Causes Dental Fluorosis

²⁶ FDA, *supra* note 2, at 52486.

²⁷ FDA, *supra* note 12, at 39867.

²⁸ This study gave the children *water*. The study’s findings would likely have been even more troubling if the children were given *candy-flavored* rinse. When drugs taste and smell like candy, many young children are inclined to swallow it, irrespective of whether they have the necessary reflexes to control doing so. *Cf.*, CDC, *supra* note 6, at 14 (stating that children are “known to swallow toothpaste deliberately when they like its taste”).

²⁹ CDC, *supra* note 6, at 16.

³⁰ A single dose is 10 mL. At a concentration of 0.05% sodium fluoride (=0.023% fluoride ion), 10 mL of mouthrinse contains 2.3 mg of fluoride ion.

³¹ ENVIRONMENTAL PROTECTION AGENCY: FLUORIDE: DOSE-RESPONSE ANALYSIS FOR NON-CANCER EFFECTS 107 (2010) (emphasis added).

58. Dental fluorosis is “a permanent, mottled discoloration of the teeth”³² that is caused by ingesting too much fluoride while the teeth are still developing. Once the teeth have finished forming, fluoride can no longer cause fluorosis. Ergo, only young children are at risk of developing this condition.

59. The first six years of life are the critical window of vulnerability for developing dental fluorosis, with fluoride exposures during the first 3 years of life being the most significant for causing fluorosis of the upper front teeth, which are the most cosmetically important teeth.³³

60. Dental fluorosis comes in various degrees of severity.³⁴ The mild forms of fluorosis cause “permanent white lines or streaks” on the teeth, whereas the severe forms of fluorosis cause “brown, gray, or black patches and pits, typically on top of an irregular tooth surface.”³⁵

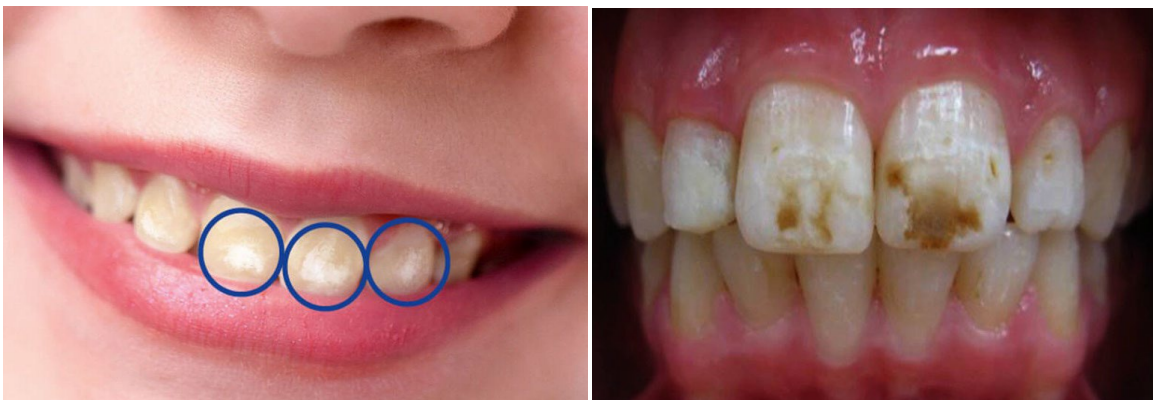


³² FDA, *supra* note 2, at 52487.

³³ Michael R. Franzman, et al., *Fluoride dentifrice ingestion and fluorosis of the permanent incisors*, 137 J AM DENT ASSOC. 645, 646 (2006).

³⁴ NATIONAL RESEARCH COUNCIL, *supra* note 11, at 103-11.

³⁵ Colgate, *Causes of Brown Spots on the Teeth*, <https://www.colgate.com/en-us/oral-health/adult-oral-care/brown-spots-on-teeth-causes> (last accessed Jan. 13, 2025).



Photos of Dental Fluorosis

61. Microscopically, “dental fluorosis is a condition of permanent hypomineralized change, with increased surface and sub-surface enamel porosity resulting from excess fluoride reaching the developing tooth prior to eruption.”³⁶ In short, “fluoride affects the forming enamel by making it more porous.”³⁷

62. The CDC agrees that ingesting fluoride mouthrinse can cause fluorosis. According to CDC, “[i]f children repeatedly swallow mouth rinses, they may develop dental fluorosis.”³⁸

63. The ingestion of fluoridated dental products is considered to be a key reason for the skyrocketing prevalence of dental fluorosis in the US. In the 1940s, dental fluorosis was a rare condition that was generally found only in areas with elevated fluoride in water. Since that time, with the advent of water fluoridation programs and fluoridated dental products, the rate of dental fluorosis has steadily increased. The most recent national survey from the CDC, conducted in

³⁶ Brian A. Burt, *The changing patterns of systemic fluoride intake*, 71 J DENT RES. 1228, 1228 (1992).

³⁷ Ana Karina Mascarenhas, *Risk factors for dental fluorosis: a review of the recent literature*, 22 PEDIATR DENT. 269, 274 (2000).

³⁸ CDC, *supra* note 10.

2015-2016, found that 68.2% of children now have some form of dental fluorosis.³⁹

64. Dental fluorosis, even in its “mild” forms, is recognized to be cosmetically objectionable when present on a child’s upper front teeth (i.e., maxillary anterior teeth).⁴⁰

65. The following are some findings from the peer-reviewed dental literature regarding the disfiguring effects of “mild” fluorosis:

- a. “Mild and moderate dental fluorosis had a negative aesthetic effect on the studied population, leading to a strong desire to seek dental treatment to change the appearance of affected teeth.”⁴¹
- b. “The key finding to emerge from this study was the negative psychosocial impact reported by some children with untreated enamel defects Over half of the children stated that they had been subject to unkind remarks about their teeth by their peers. A number of children described a reluctance to smile or a lack of confidence.”⁴²
- c. “Fluorosis was associated with increased parental dissatisfaction with overall appearance, color, and blotchiness of their children’s teeth.”⁴³

³⁹ Hung et al., *supra* note 21.

⁴⁰ Susan O. Griffin et al., *Esthetically objectionable fluorosis attributable to water fluoridation*, 30 COMMUNITY DENT ORAL EPIDEMIOL. 199, 202-03 (2002).

⁴¹ Frederico Omar Gleber-Netto, et al. *Assessment of aesthetic perception of mild and moderate dental fluorosis levels among students from the Federal University of Minas Gerais-UFGM, Brazil*, 9 ORAL HEALTH PREV DENT 339, 339 (2011).

⁴² H.D. Rodd, et al., *Seeking children's perspectives in the management of visible enamel defects*, 21 INT J PAEDIATR DENT. 89, 93 (2011); *see also* Zoe Marshman, et al., *The impact of developmental defects of enamel on young people in the UK*, 37 COMMUNITY DENT ORAL EPIDEMIOL. 45 (2008).

⁴³ Steven M. Levy, et al., *Factors associated with parents’ esthetic perceptions of children’s mixed dentition fluorosis and demarcated opacities*, 27 PEDIATR DENT. 486, 486 (2005).

- d. “The pupils’ feedback was extremely useful, revealing that they believed the ‘marks’ on the teeth to be due to poor oral hygiene, despite a preliminary tutorial which indicated this was not the case.”⁴⁴
- e. “Our studies of esthetic perceptions of dental fluorosis found that members of the public had strong preferences about variations from normal tooth appearance. For example, all respondents had a preference for teeth with normal color over teeth with mild fluorosis”⁴⁵
- f. “Results show that not only is fluorosis noticeable, but it may be more of an esthetic concern than the other conditions (e.g. isolated opacities, tetracycline staining, or various types of malocclusion).”⁴⁶
- g. “A strong association between fluorosis and parental satisfaction was evident, even at a low level of severity.”⁴⁷
- h. “South Australian children 10- to 17-years-old were able to recognize very mild and mild fluorosis and register changes in satisfaction with the colour and appearance of teeth. Even mild changes were associated with psycho-behavioural impacts.”⁴⁸
- i. “[O]bservers felt that the appearance would increasingly embarrass the

⁴⁴ Maura Edwards, et al., *An assessment of teenagers’ perceptions of dental fluorosis using digital stimulation and web-based testing*, 33 COMMUNITY DENT ORAL EPIDEMIOL. 298, 305(2005).

⁴⁵ Steven M. Levy, *An update on fluorides and fluorosis*, 69 J CAN DENT ASSOC. 286, 287 (2003).

⁴⁶ Carrie B. McKnight, et al., *A pilot study of esthetic perceptions of dental fluorosis vs. selected other dental conditions*, 65 ASDC J DENT CHILD 233, 233 (1998).

⁴⁷ James A. Lalumandier & R. Gary Rozier, *Parents’ satisfaction with children’s tooth color: fluorosis as a contributing factor*, 129 J AM DENT ASSOC. 1000, 1003 (1998).

⁴⁸ John Spencer, et al., *Water fluoridation in Australia*, 13 COMMUNITY DENT HEALTH 27 (1996).

child as the TF score increased.”⁴⁹

66. Due to the objectionable appearance of fluorosis, many people with the condition pay for cosmetic treatment (e.g., abrasion of the tooth surface in mild cases, and veneers in severe cases). This treatment can be expensive and beyond the financial means for some families.

67. It is too early to determine whether Plaintiff’s daughter has suffered dental fluorosis as a result of her use of Hello Rinse because her permanent teeth have only recently begun to erupt. (The permanent teeth, not baby teeth, are at risk of fluorosis from mouthrinse ingestion.)

C. Ingesting Fluoride Toothpaste Can Cause Stomach Flu Symptoms

68. Ingesting too much fluoride mouthrinse can cause symptoms of acute toxicity that mimic the symptoms of stomach flu, including nausea, upset stomach, diarrhea, and vomiting.

69. According to a review in the *Journal of Public Health Dentistry*, “Parents or caregivers may not notice the symptoms associated with mild fluoride toxicity or may attribute them to colic or gastroenteritis, particularly if they did not see the child ingest fluoride. Similarly, because of the nonspecific nature of mild to moderate symptoms, a physician’s differential diagnosis is unlikely to include fluoride toxicity without a history of fluoride ingestion.”⁵⁰

70. The mechanism by which fluoride causes stomach flu symptoms has been described as follows: “When above normal amounts of fluoride are ingested, the fluoride combines with hydrochloric acid in the stomach and forms hydrofluoric acid. As a result, the hydrofluoric acid has a burning effect on the gastric lining causing gastrointestinal (GI) symptoms such as nausea, vomiting, abdominal cramping, and discomfort.”⁵¹

⁴⁹ Paul J. Riordan, *Perceptions of dental fluorosis*, 72 J DENTAL RES 1268, 1268 (1993).

⁵⁰ Shulman & Wells, *supra* note 8, at 157.

⁵¹ Mary D. Cooper & Connie M. Kracher, *Are our patients guzzling too much fluoride?*, RDH MAGAZINE, Feb. 1, 1997, <https://www.rdhmag.com/patient-care/rinses->

71. According to FDA Commissioner, Dr. Marty Makary, “[f]or the same reason that fluoride may kill bacteria on teeth, it may also kill intestinal bacteria important for a child’s health.”⁵²

72. As with all toxicants, the dose of fluoride that causes symptoms of toxicity varies considerably across the population, with some children being much more vulnerable, and other children being much more resistant, than the “average child.”⁵³

73. Symptoms of nausea and gastrointestinal distress have been reported at single doses as low as 0.1 mg/kg.⁵⁴ A 2 year-old-child of average weight (~12 kg) will ingest this much fluoride by swallowing just over half of a single 10 mL dose of Hello Rinse.

74. In *adults*, a one-time ingestion of as little as 3 milligrams of fluoride in one sitting (or the equivalent of 13 mL of Hello Rinse) has been found to cause “widespread” erosions of the gastric mucosa in the stomach.⁵⁵ The dose that causes erosions in the stomach of children has not been studied (due to ethical constraints) but will almost certainly be less than 3 mg due to lower bodyweight and smaller stomach space.

75. If a 2 year-old-child ingests just 5 mL of Hello Rinse, or half of a single dose, the National Capital Poison Center recommends that the child take “Two tablets of chewable calcium or calcium plus vitamin D supplement,” “Four ounces of milk,” or “One tablespoon of liquid

[pastes/article/16406858/are-our-patients-guzzling-too-much-fluoride](https://www.fda.gov/oc/pastes/article/16406858/are-our-patients-guzzling-too-much-fluoride).

⁵² See *supra* note 22.

⁵³ E.g., H.G. Eichler, et al., *Accidental ingestion of NaF tablets by children--report of a poison control center and one case*, 20 INT J CLIN PHARMACOL THER TOXICOL. 334 (1982). Cf. C.J. Spak, et al., *Studies of human gastric mucosa after application of 0.42% fluoride gel*, 69 J DENT RES. 426 (1990).

⁵⁴ Kenji Akiniwa, *A Re-examination of acute toxicity of fluoride*, 30 FLUORIDE 89 (1997).

⁵⁵ Spak, *supra* note 53.

antacid containing magnesium or aluminum” in order to help prevent “nausea, vomiting, diarrhea.”⁵⁶

D. Half a Bottle of Hello Rinse Has Enough Fluoride to Kill a Toddler

76. Fluoride is a “protoplasmic poison”⁵⁷ that can kill humans at doses not that much higher than arsenic.⁵⁸ The potency of fluoride’s acute toxicity is why fluoride has been used as the active ingredient in rodenticides (to kill rodents) and insecticides (to kill bugs).⁵⁹ As far back as 1895, it was observed that “sodium fluoride is an active poison for micro-organisms of all kinds, algae, and nerves and muscles of the higher organisms.”⁶⁰

77. The “Probable Toxic Dose” (“PTD”) for fluoride is 5 mg/kg.⁶¹ The PTD “is defined as the dose of ingested fluoride that should trigger immediate therapeutic intervention and hospitalization because of the likelihood of serious toxic consequences.”⁶² It is the “minimum dose that could cause toxic signs and symptoms, including death, and that should trigger immediate

⁵⁶ See <https://triage.webpoisoncontrol.org/> (last accessed Jan. 13, 2025).

⁵⁷ Editorial, *Chronic fluorine intoxication*, 123 J AM DENT ASSOC. 150, 150 (1943).

⁵⁸ The CDC states that “[a]s little as 1–2.5 mg/kg of arsenic trioxide is a potentially fatal dose.” CDC, *Medical Management Guidelines for Arsenic (As) and Inorganic Arsenic Compounds*, <https://wwwn.cdc.gov/TSP/MMG/MMGDetails.aspx?mmgid=1424&toxid=3>. This is only slightly lower than the potentially fatal dose of fluoride (5 mg/kg), as discussed below. See also Floyd DeEds, *Fluorine in relation to bone and tooth development*, 33 J AM DENT ASSOC. 568, 570 (1936) (“Such a comparison of toxicity data suggests that fluorine, lead and arsenic belong to the same group, as far as ability to cause some symptom of toxicity in minute dosage is concerned.”).

⁵⁹ KAJ ROHOLM, FLUORINE INTOXICATION: A CLINICAL HYGIENIC STUDY WITH A REVIEW OF THE LITERATURE AND SOME EXPERIMENTAL INVESTIGATIONS 301 (1937).

⁶⁰ Herbert B. Baldwin, *The toxic action of sodium fluoride*, 21 J AM CHEM SOC. 517, 521 (1899) (quoting Czrellitzer 1895).

⁶¹ Gary M. Whitford, *Fluoride in dental products: safety considerations*, 66 J DENT RES. 1056, 1056 (1987).

⁶² *Id.*

therapeutic intervention and hospitalization.”⁶³

78. Due to person-to-person variations in sensitivity to fluoride toxicity, not all people who ingest 5 mg/kg will experience significant toxicity. But, “if it is even suspected that 5.0 mg/kg or more of fluoride has been ingested, then it should be assumed that an emergency exists. Appropriate therapeutic measures and hospitalization should be instituted immediately.”⁶⁴

79. A bottle of Hello Rinse contains 109 milligrams of fluoride. A 1 year-old-child of average weight (~9 kg) would exceed the PTD if he ingested just 41% of Defendant’s fruit- and candy-flavored rinse, while a 2 year-old-child of average weight (~12 kg) would exceed the PTD if he ingested 55%.

80. Each year there are over 4,000 reports to poison control centers related to ingestion of fluoride mouthrinses.⁶⁵ The vast majority of these calls are made on behalf of very young children.

81. The number of poisoning incidents from consumer products reported to poison control centers is recognized to “likely underestimate the total incidence and severity of poisonings.”⁶⁶ This is the case even for poisonings that cause outcomes as severe as death.⁶⁷

⁶³ *Id.* at 1057.

⁶⁴ *Id.*

⁶⁵ David D. Gummin et al., *2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report*, 59 CLIN TOXICOL (Phila) 1282, 1448 (2020); David D. Gummin et al., *2021 Annual Report of the National Poison Data System© (NPDS) from America's Poison Centers: 39th Annual Report*, 60 CLIN TOXICOL (Phila) 1381, 1581 (2021).

⁶⁶ Arthur Chang, et al., *Cleaning and Disinfectant Chemical Exposures and Temporal Associations with COVID-19 — National Poison Data System, United States, January 1, 2020–March 31, 2020*, 69 MMWR MORB MORTAL WKLY REP. 16 496, 496-97 (2020).

⁶⁷ Christopher Hoyte, Medical Director of the Rocky Mountain Poison Center, Presentation to FDA Workshop “Defining ‘Candy-Like’ Nonprescription Drug Products,” Oct. 30, 2023, p. 232.

82. Consistent with the general recognition that poison control data underestimates the true extent and severity of poisonings, the reported number of poisonings from fluoride mouthrinse is also believed to “underestimate” the true extent of fluoride poisonings due to “substantial underreporting” of such incidents.⁶⁸

83. Nevertheless, the FDA has cited the large number of poison control reports for fluoride mouthrinses as a justification for requiring a poison warning on these products.⁶⁹ FDA’s required poison warning states as follows: “Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.” 21 C.F.R. § 355.50(c)(2).

E. Other Health Concerns with Early Life Exposure to Fluoride

84. Acute toxicity and dental fluorosis are not the only health concerns with excess ingestion of fluoride.

85. In 2006, the National Research Council (“NRC”) of the National Academies of Science published a comprehensive review of fluoride toxicology which concluded, among other things, that excess fluoride exposure weakens bone, damages the brain, and disrupts the endocrine system, including the thyroid gland.⁷⁰ According to the NRC, fluoride has been credibly associated with impaired thyroid function in susceptible humans at doses as low as 0.01 to 0.03 mg/kg/day,⁷¹ which is less than many children will routinely ingest from using fluoride mouthrinse.⁷²

⁶⁸ Shulman & Wells, *supra* note 8, at 157.

⁶⁹ FDA, *supra* note 2, at 52486.

⁷⁰ NATIONAL RESEARCH COUNCIL, *supra* note 11, at 178-80, 220-22 & 260-66.

⁷¹ *Id.* at 263 (“In humans, effects on thyroid function were associated with fluoride exposures of 0.05-0.13 mg/kg/day when iodine intake was adequate and 0.01-0.03 mg/kg/day when iodine intake was inadequate.”).

⁷² A 2 year-old-child of average weight (~12 kg) will ingest 0.03 mg/kg from ingesting just 1/6th

86. Another endocrine effect of fluoride exposure that the NRC flagged is impaired glucose metabolism, which is believed to be caused by fluoride's "inhibition of insulin production."⁷³ According to the NRC, blood fluoride levels of 0.1 mg/L are credibly associated with this effect.⁷⁴ A preschool child who ingests as little as 1/3 of a single dose of Hello Rinse will have blood fluoride levels that temporarily approximate or exceed this level.⁷⁵

87. In August of 2024, the National Toxicology Program ("NTP"), which is part of the National Institutes of Health, published a systematic review in which it concluded that excess fluoride exposure is "consistently associated with reduced IQ in children."⁷⁶

88. In January of 2025, NTP scientists published a meta-analysis of 74 human studies on fluoride and IQ in the journal *JAMA Pediatrics*.⁷⁷ The NTP analysis "found inverse associations and a dose-response relationship between fluoride measurements in urine and drinking water and children's IQ across the large multicountry epidemiological literature."

89. The NTP has flagged mouthrinse as a source of childhood fluoride exposure that could contribute to the risk of neurodevelopmental problems. According to the NTP, "children may be getting more fluoride than they need because they now get fluoride from many sources including treated public water, water-added foods and beverages, teas, toothpaste, floss, and

of a single 10 mL dose of Firefly rinse.

⁷³ *Id.* at 264.

⁷⁴ *Id.*

⁷⁵ See Jan Ekstrand et al., *Plasma fluoride concentrations in pre-school children after ingestion of fluoride tablets and toothpaste*, 17 CARRIES RES. 379 (1983).

⁷⁶ NATIONAL TOXICOLOGY PROGRAM, NTP MONOGRAPH ON THE STATE OF THE SCIENCE CONCERNING FLUORIDE EXPOSURE AND NEURODEVELOPMENT AND COGNITION: A SYSTEMATIC REVIEW. Available online at https://ntp.niehs.nih.gov/sites/default/files/2024-08/fluoride_final_508.pdf.

⁷⁷ Kyla Taylor et al., *Fluoride exposure and children's IQ scores: A systematic review and meta-analysis*, JAMA PED. doi: 10.1001/jamapediatrics.2024.5542 (published online on Jan. 6, 2025).

mouthwash, and the combined total intake of fluoride may exceed safe amounts.”⁷⁸

90. On September 24, 2024, after hearing extensive expert testimony about NTP’s findings and other recent research, the Honorable Judge Edward Chen from the U.S. District Court for the Northern District of California concluded that the addition of fluoride to drinking water “poses an unreasonable risk of reduced IQ in children.” *Food & Water Watch, Inc. v. United States EPA*, No. 17-cv-02162-EMC, 2024 U.S. Dist. LEXIS 172635, at *4 (N.D. Cal. Sep. 24, 2024).

91. Judge Chen’s detailed 80-page decision, along with the NRC and NTP reports, further highlights the need to limit children’s ingestion of fluoride.

F. The Problem with Presenting Fluoride Mouthrinse as a Candy-Like Drug

92. It is well recognized that presenting drugs as “candy-like” products increases the risk of overdose, particularly for young children. This problem has long been specifically flagged in the context of fluoridated dental products.

93. In 1992, the *Journal of Public Health Dentistry* published a consensus statement which read, in part, “The use of flavors that may increase the ingestion of fluoridated dentifrices by young children should be strongly discouraged.”⁷⁹

94. In 1994, the World Health Organization stated, “the production of candy-like flavours . . . should not be encouraged for use by children, as they may lead to an excessive ingestion of fluoride.”⁸⁰

95. In 1997, the *Journal of Public Health Dentistry* published a review, which stated

⁷⁸ National Toxicology Program, *Fluoride Exposure: Neurodevelopment and Cognition*, <https://ntp.niehs.nih.gov/whatwestudy/assessments/noncancer/completed/fluoride> (last accessed Jan. 13, 2025).

⁷⁹ James W. Bawden, et al. *Changing patterns of fluoride intake. Proceedings of the workshop. Part II*, 71 J PUBLIC HEALTH DENT. 1212, 1221 (1992).

⁸⁰ WORLD HEALTH ORGANIZATION, *supra* note 4, at 28.

“The use of flavored consumer fluoride products increases the possibility that a child will ingest a toxic dose of fluoride.”⁸¹

96. Studies have empirically tested, and confirmed, that adding candy flavor to toothpaste increases the amount of paste that children add to their brush, as well as the amount of toothpaste that they ingest.⁸² Similar studies have not been conducted on candy-flavored mouthrinses. The absence of such studies is likely a result, in part, of the bioethical problem of intentionally exposing preschool children to a product that is contraindicated for this population.

97. According to the FDA, marketing dangerous products to children through the use of candy or food flavoring is a “misleading” marketing tactic that can render a product “misbranded” under the FDCA.⁸³

G. FDCA Requirements for Fluoride Mouthrinse

General Requirements

98. The FDCA prohibits companies from selling over-the-counter drugs that are “misbranded.” 21 U.S.C. § 331(a).

99. A drug is misbranded if it has labeling that “is **false or misleading** in any

⁸¹ Shulman & Wells, *supra* note 8, at 150.

⁸² Steven M. Levy, et al., *A pilot study of preschoolers' use of regular-flavored dentifrices and those flavored for children*, 14 PEDIATR DENT. 388 (1992); Steven M. Adair, et al., *Comparison of the use of a child and an adult dentifrice by a sample of preschool children*, 19 PEDIATR DENT. 99 (1997); Claudia A. Kobayashi, et al., *Factors influencing fluoride ingestion from dentifrice by children*, 39 COMMUNITY DENT ORAL EPIDEMIOL. 426 (2011); Carrie A. Strittholt, et al., *A randomized clinical study to assess ingestion of dentifrice by children*, 75 REGUL TOXICOL PHARMACOL. 66 (2016).

⁸³ E.g., FDA Warning Letter to Electric Lotus, LLC, Nov. 29, 2018, *available at*: <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/electric-lotus-llc-568710-11292018> (warning liquid tobacco companies that their use of candy flavoring is “misleading” and “increases the likelihood that children will ingest the product as a food”).

particular.” 21 U.S.C. § 352(a)(1) (emphasis added).

100. A drug is also misbranded if “any word, statement, or other information required . . . to appear on the label or labeling is not **prominently** placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.” 21 U.S.C. § 352(c) (emphasis added).

101. Under the regulations issued pursuant to the FDCA, the warnings and directions on a label will fail to meet the prominence test if there is:

- Insufficiency of label space for the prominent placing of such word, statement, or information, resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;
- Insufficiency of label space for the prominent placing of such word, statement, or information, resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device.

21 C.F.R. § 201.15(a)(4)-(5).

102. An over-the-counter drug is “not misbranded” if it satisfies “each of the conditions contained in any applicable monograph” **and** is “labeled in compliance” with 21 U.S.C. § 352 and the regulations issued pursuant thereto. 21 C.F.R. § 330.1(c)(1). Thus, a drug can meet each of the conditions of an applicable Monograph and still be misbranded if it has additional text on the label that is false and misleading, or fails to display the required warnings and directions in a sufficiently prominent manner.

Specific Requirements

103. The FDA has issued a Monograph for anti-cavity dental products, including fluoride mouthrinse. 21 C.F.R. §§ 355.50 & 355.55.

104. The FDA requires that all fluoride mouthrinse products provide the following warning: “Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.” 21 C.F.R. § 355.50(c)(2). The FDA requires that the first sentence of this warning be in bold type. *Id.*

105. The FDA requires that fluoride mouthrinses containing 0.05% sodium fluoride⁸⁴ provide the following directions: “Adults and children 6 years of age and older: Use once a day after brushing your teeth with a toothpaste. Vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out. Do not swallow the rinse. Do not eat or drink for 30 minutes after rinsing. Instruct children under 12 years of age in good rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age: Consult a dentist or doctor.” 21 C.F.R. § 355.50(d)(2)(ii).

106. The FDA also requires that “the following statement shall be prominently placed on the principal display panel” of all fluoride mouthrinses: “IMPORTANT: Read directions for proper use.” 21 C.F.R. § 355.55.

Things that the FDA Does Not Require

107. The FDA does not require fluoride mouthrinse to taste and smell like candy or fruit juice.

108. The FDA does not require the labeling of fluoride mouthrinse to boast that its kids-friendly favor “tastes awesome,” “tastes magical,” and “tastes delicious.”

109. The FDA does not require the labeling of fluoride mouthrinse to use language that encourages parents and caregivers to think of the product as harmless for children.

⁸⁴ This is the concentration of Hello Rinse.

H. The Deceptive Attributes of Hello Rinses



110. Hello Rinse has the following deceptive attributes which individually and collectively convey the deceptive impression that the product is specially formulated to be safe for young children:

- a. The label makes repeated references to “kids” and “little brushers” to deceptively convey that the product is age-appropriate for young children.
- b. The label boasts of having juice and candy attributes and flavors (“Wild Strawberry” and “Unicorn Splash - Bubble Gum”) that will appeal to young children. This signals that product is age-appropriate for young children, and, since juice and candy are things that children *ingest*, signals that the sweet-

tasting liquid in the bottle is safe to ingest.

- c. The label uses language that deceptively implies the product is safe to swallow, including “naturally friendly,” “thoughtfully formulated,” and “no alcohol. no dyes. no artificial sweeteners. no artificial flavors. no SLS/sulfates. no brainer.”
- d. The language on the label is written in a playful, silly, kid-appealing tone that deceptively conveys the impression that this is a harmless product that does not need to be handled with caution or care (e.g., “tastes like rainbows and sunshine (aka bubble gum),” “tastes so delicious they’ll rush to rinse,” “your swish come true,” “tastes magical,” and “rinse away the nasty bits”).
- e. The back label gives far more prominence to puffery about the product than to FDA’s required warnings and directions. The font size, boldness, sharpness of text, and location of the puffery effectively drowns out and conceals the warnings and directions.
- f. The FDA-required warnings and directions on the back label are displayed in a manner (e.g., small font, blurry text, minimal color contrast between text and background, and minimal space between the letters) that makes them difficult, if not impossible, for ordinary consumers to read.⁸⁵
- g. The front label conceals the notice that FDA requires to be “prominently displayed.” *See* 21 C.F.R. § 355.55.

111. The deceptive attributes identified in the foregoing paragraph, individually and collectively caused Plaintiff to falsely believe that Hello Rinse is specially formulated to be safe

⁸⁵ The blurriness of the directions and warnings, while actionable for each unit, does vary, with some units being so blurry that the few consumers who take the time and effort to strain their eyes and concentration to read the already non-conspicuous text will have even greater difficulty doing so.

for young children.

112. Plaintiff relied upon these deceptive attributes, both individually and collectively, in deciding to purchase Hello Rinse.

113. Had Plaintiff known that fluoride mouthrinses are contraindicated for children under six due to an unacceptable risk profile, Plaintiff would *not* have purchased Hello Rinse, or any other fluoride rinse.

I. Reasonable Consumers Are Misled by Defendants' Marketing Tactics

114. Most parents are unaware of the recommended amount of kids' fluoride products that young children should use and the reasons for these recommendations.⁸⁶ This increases the susceptibility of consumers to Defendants' deceptive marketing tactics because the safety, or lack thereof, of fluoride mouthrinse ingestion is not within the ken of most people.

115. Peer-reviewed reports in the scientific literature have described the marketing tactics that Defendants use to sell kids' fluoride toothpastes as "misleading" and "confusing."⁸⁷ These tactics include the use of fruit imagery to depict fluoride products.

116. The fact that Defendant places the FDA-required warnings and directions in fine print on the back of the product does not cure the much more prominent representations on the front of the product that run counter to, and undermine, said warnings and directions. This is especially so given the small, blurry, hard to read formatting in which Defendant presents this information.

117. In the analogous context of fluoride toothpastes, public health researchers have warned that "the small size and the minimally accessible placement of the warning labels" on the

⁸⁶ Annie Y. Chen, et al., *Appropriate Fluoride Toothpaste Application: Improving Caregiver Compliance*, 40 PEDIATRIC. DENT. 412, 415-16 (2018).

⁸⁷ Basch & Rajan, *supra* note 9, at 316; Chen, *supra* note 86, at 416.

back of kid's fluoride toothpaste tubes "presents a problem for parents and guardians of young children who may miss this important information."⁸⁸

118. Courts have recognized that deceptive representations on the front of a label are not cured or absolved by including correct information in the fine print on the back, even when the fine print provides all of the requisite information required by the FDA. *See, e.g., Cooper v. Anheuser-Busch, LLC*, 553 F. Supp. 3d 83, 107-08 (S.D.N.Y. 2021) (citing cases).

119. As the Seventh Circuit explained in *Bell v. Publix Super Mkts., Inc.*, 982 F.3d 468, 476, 481 (7th Cir. 2020):

Consumer-protection laws do not impose on average consumers an obligation to question the labels they see and to parse them as lawyers might for ambiguities, especially in the seconds usually spent picking a low-cost product. *See, e.g., Danone, US, LLC v. Chobani, LLC*, 362 F. Supp. 3d 109, 123 (S.D.N.Y. 2019) ("[A] parent walking down the dairy aisle in a grocery store, possibly with a child or two in tow, is not likely to study with great diligence the contents of a complicated product package, searching for and making sense of fine-print disclosures Nor does the law expect this of the reasonable consumer. . . . We doubt it would surprise retailers and marketers if evidence showed that many grocery shoppers make quick decisions that do not involve careful consideration of all information available to them. *See, e.g., U.S. Food & Drug Admin., Guidance for Industry: Letter Regarding Point of Purchase Food Labeling* (Oct. 2009) ("FDA's research has found that with [Front of Package] labeling, people are less likely to check the Nutrition Facts label on the information panel of foods (usually, the back or side of the package).")

J. Defendant's Deceptive Conduct Caused Economic Injury to Plaintiff and Class Members

120. Defendant made the false, misleading, and deceptive representations, omissions, and tactics described above to induce parents and caregivers of young children to purchase Hello Rinse who would not have purchased the product if they knew the product is contraindicated for

⁸⁸ Basch & Rajan, *supra* note 9, at 318.

children under six.

121. Defendant was, and remains, unjustly enriched each time parents and caregivers act on Defendant's false, misleading, and deceptive packaging by purchasing Hello Rinse for children for whom the product is contraindicated.

122. Had Plaintiff known that fluoride mouthrinses are contraindicated for children under 6 due to an unacceptable risk profile, they would not have purchased Hello Rinse, or any other fluoride rinse, because they would not knowingly have allowed their children to be exposed to a drug that the FDA considers too dangerous for young children to safely use.

123. Plaintiff and similarly situated class members have thus suffered injury in fact by losing money on their purchase of a product that they would never have purchased or allowed their children to use had they not been deceived.

124. To the extent that fluoride mouthrinse is considered to have *any* value for children under 6 (which Plaintiff disputes given the overwhelming evidence of an unacceptable risk profile for this young and vulnerable age group), the value is significantly less than what Plaintiff and putative class members paid for it. Plaintiff and class members thereby suffered economic loss by, at a minimum, purchasing the product for far more than its value.

125. Plaintiff and the putative class do not seek recovery for any personal injuries that they or their children may have suffered from using Hello Rinse, including any emotional harm stemming therefrom.

CLASS ALLEGATIONS

126. Pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3), Plaintiff brings this action on behalf of the following Multi-State Class: All persons in Arizona, California, Connecticut, Florida, Hawaii, Idaho, Illinois, Minnesota, Missouri, New Jersey, New York,

Virginia, Washington State, and Washington D.C., who purchased Hello Rinse for children under the age of 6 within the applicable statutes of limitation and who did so in the absence of direction from a dentist, doctor, or health care provider.

127. As used herein, the term “Class” shall refer to the aforementioned putative class.

128. Excluded from the Class are Defendant, its parents, subsidiaries, affiliates, officers, and directors; those who purchased the Products for resale; those who make a timely election to be excluded from the classes, and the judge to whom the case is assigned and any immediate family members thereof.

129. The Class Period begins on the date established by the Court’s determination of any applicable statute of limitations, after consideration of any tolling, discovery, knowing concealment, and accrual issues, and ending on the date of entry of judgment.

130. Plaintiff reserves the right to amend the definition of the Class if discovery or further investigation reveals that the Class should be expanded or otherwise modified.

131. **Numerosity**: The members of the Class are so numerous that joinder of all class members is impracticable. Class Members may be notified of the pendency of this action by recognized, Court-approved notice dissemination methods, which may include U.S. mail, electronic mail, Internet postings, and/or published notice.

132. **Predominance of Common Questions of Law and Fact**: Questions of law and fact that are common to the members of the Class predominate over questions that are specific to individual members. These common questions of law and fact include, but are not limited to, the following:

- a) Whether the FDCA preempts claims that the voluntarily added components of the PRODUCTS’ packaging and labeling are false, misleading, and/or deceptive;

- b) Whether the attributes of Hello Rinse that are not required by the FDA Monograph are false, misleading, and/or deceptive;
- c) Whether Defendant knew or should have known that the packaging of Hello Rinse is false, misleading, and/or deceptive;
- d) Whether Defendant has violated the state consumer protection statutes alleged herein;
- e) Whether Defendant was unjustly enriched;
- f) Whether Plaintiff and Class members have suffered an ascertainable loss of monies or property or other value as a result of Defendant's deceptive conduct;
- g) Whether Plaintiff and Class members are entitled to relief, and, if so, the nature of such relief.

133. The consumer protection laws in the states within the Class are materially identical with respect to the causes of action for deceptive trade practices alleged herein. Thus, the same deceptive conduct by Defendant that violates Illinois's Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505, *et seq.*, simultaneously violates the consumer protection laws of the other identified states.

134. **Typicality**: Plaintiff's claims are typical of those of other Class members because, like all members of the Class, Plaintiff purchased Hello Rinse for his child under 6 and sustained economic loss as a result. Defendant's conduct that gave rise to the claims of Plaintiff is the same for Plaintiff and all members of the Class.

135. **Adequacy**: Plaintiff will fairly and adequately protect the interests of the Class and has retained counsel that is experienced in litigating complex class actions. Plaintiff has no interests which conflict with those of the Class. Plaintiff and counsel are aware of their fiduciary responsibilities to the Class members and are determined to diligently discharge those duties by

vigorously seeking the maximum possible recovery for Class members.

136. **Superiority**: A class action is superior to any other available means for the fair and efficient adjudication of this controversy for the following reasons:

- a. The extent of economic loss suffered by each individual member of the Class does not justify the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Defendant's conduct;
- b. Even if individual members of the Class had the resources to pursue individual litigation, it would pose a crushing burden on the court system for these cases to be litigated on an individual basis;
- c. Absent a class action mechanism, Plaintiff and members of the Class will continue to suffer harm as a result of Defendant's unlawful conduct because individual litigation is wholly impractical and cost prohibitive; and
- d. This action presents no difficulty that would impede its management by the Court as a class action.⁸⁹

⁸⁹ Each claimant's eligibility for relief can be determined through self-identifying affidavits, a mechanism that courts have widely endorsed in cases, such as the one at bar, involving low-priced consumer goods. *See, e.g., Beaton v. SpeedyPC Software*, 907 F.3d 1018, 1030 (7th Cir. 2018); *Mullins v. Direct Dig., Ltd. Liab. Co.*, 795 F.3d 654, 662 (7th Cir. 2015); *Langan v. Johnson & Johnson Consumer Cos.*, 897 F.3d 88, 91 n.2 (2d Cir. 2018); *Benson v. Newell Brands, Inc.*, No. 19 C 6836, 2021 U.S. Dist. LEXIS 220986, at *30-32 (N.D. Ill. Nov. 16, 2021); *Knapper v. Cox Communs., Inc.*, 329 F.R.D. 238, 246 n.2 (D. Ariz. 2019); *Hasemann v. Gerber Prods. Co.*, No. 15-CV-2995 (MKB) (RER), 2019 U.S. Dist. LEXIS 28770, at *53-54 (E.D.N.Y. Feb. 20, 2019); *Zakaria v. Gerber Prods. Co.*, No. LA CV15-00200 JAK (Ex), 2016 U.S. Dist. LEXIS 184861, at *50 (C.D. Cal. Mar. 23, 2016); *Krueger v. Wyeth, Inc.*, 310 F.R.D. 468, 476 (S.D. Cal. 2015); *Suchanek v. Sturm Foods, Inc.*, 311 F.R.D. 239, 259-60 (S.D. Ill. 2015); *Morales v. Kraft Foods Grp., Inc.*, No. LA CV14-04387 JAK (PJWx), 2015 U.S. Dist. LEXIS 177918, at *35-38 (C.D. Cal. June 23, 2015); *In re Conagra Foods, Inc.*, 302 F.R.D. 537, 566-67 (C.D. Cal. 2014); *Brown v. Hain Celestial Grp., Inc.*, No. C 11-03082 LB, 2014 U.S. Dist. LEXIS 162038, at *29-30 (N.D. Cal. Nov. 18, 2014).

FIRST CAUSE OF ACTION

**False Pretenses, Promises, and Misrepresentations in Violation of the
Illinois Consumer Fraud and Deceptive Trade Practices Act
815 ILCS 505/1, et seq.**

137. Plaintiff incorporates the preceding paragraphs as if fully written herein.

138. Plaintiff brings this claim individually and on behalf of the Illinois members of the Multi-State Class.

139. Plaintiff and Class members are persons within the context of the Illinois Consumer Fraud and Deceptive Trade Practices Act (“ICFA”), 815 ILCS § 505/1(c).

140. Defendant is a person within the context of the ICFA, 815 ILCS § 505/1(c).

141. At all times relevant hereto, Defendant was engaged in trade or commerce as defined under the ICFA, 815 ILCS § 505/1(f).

142. Plaintiff and Class members are “consumers” who purchased Hello Rinse for personal, family, or household use within the meaning of the ICFA, 815 ILCS § 505/1(e).

143. The ICFA prohibits “[u]nfair methods of competition and unfair or deceptive acts or practices,” which includes “the use or employment of any . . . false pretense, false promise, misrepresentation . . . of any material fact.” 815 ILCS 505/2.

144. A “claim for ‘deceptive’ business practices under the [ICFA] does not require proof of intent to deceive.” *Wigod v. Wells Fargo Bank, N.A.*, 673 F.3d 547, 575 (7th Cir. 2012) (citation omitted). The defendant, however, must intend for consumers to rely on the aspects of the labeling that are alleged to be deceptive.

145. As with other sophisticated corporate entities, Defendant intentionally designs the packaging and labeling of its products to entice the target audience to purchase said products.

146. Defendant has violated, and continues to violate, the ICFA by using deceptive acts and practices to sell its Hello Rinse. As described above, including but not limited to paragraph

109, Defendant's labeling of the Hello Rinse implies the false pretense, false promise, and misrepresentation that the product is specially formulated to be safe for young children.

147. Defendant intends for consumers of Hello Rinse to rely on the deceptive attributes of the labeling. Whether or not Defendant knows these attributes are deceptive, it specifically chose these attributes based on their ability to persuade consumers, including Plaintiff and Class members, to purchase the product.

148. Plaintiff and Illinois Class members purchased Hello Rinse for their preschool children based on their reasonable reliance on Defendant's deceptive labeling.

149. Plaintiff and Illinois Class Members suffered economic harm as a proximate result of Defendant's violations of the ICFA by purchasing a product they never would have purchased absent the deceptive practices given FDA's contraindication and the unacceptable risk the product poses to young children.

150. Alternatively, to the extent Hello Rinse is considered to have value for children six under six despite its contraindication and unacceptable risk profile, Plaintiff and Illinois Class Members were harmed by purchasing a product whose true value, absent the deceptive conduct, was far less than what they paid.

151. Through its deceptive acts and practices, Defendant has been unjustly enriched, and continues to be unjustly enriched, by unfairly obtaining money from members of the Class.

152. Based on Defendant's deceptive acts or practices, Plaintiff and the Illinois Class members are entitled to relief under 815 ILCS §505/10a.

SECOND CAUSE OF ACTION

**Concealment and Suppression of Material Facts in Violation of the
Illinois Consumer Fraud and Deceptive Trade Practices Act
815 ILCS 505/1, et seq.**

153. Plaintiff incorporates the preceding paragraphs as if fully written herein.

154. Plaintiff brings this claim individually and on behalf of the Illinois members of the Class.

155. The ICFA prohibits “[u]nfair methods of competition and unfair or deceptive acts or practices,” which includes “concealment, suppression or omission of any material fact.” 815 ILCS 505/2.

156. Defendant has violated the ICFA by concealing and suppressing material facts in the packaging of Hello Rinse. Specifically, Defendant has concealed and suppressed the directions and warnings for the product, including that children under 6 are not to use the product, through the totality of the following three deceptive actions: (1) failing to provide a prominent notice regarding the importance of reading the directions; (2) drowning out the directions and warnings on the back of the label by giving much more prominence to puffery and promotional claims; and (3) displaying the directions and warnings on the back label in a way that makes the text difficult, if not impossible, for ordinary consumers to read, including using small blurry text that has minimal space between the letters as well as minimal contrast with the background.

157. The aforementioned concealment and suppression of the directions and warnings simultaneously violates the ICFA and FDCA, including 21 U.S.C. § 352(c), 21 C.F.R. § 201.15(a)(4)-(5), and 21 C.F.R. § 355.55.

158. Given Defendant’s concealment of the FDA-required directions and warnings, most consumers do not know that Hello Rinse is contraindicated for children under 6 years of age.

159. Defendant intends for consumers to rely on its concealment and suppression of the warnings and directions. Consistent with this intention, consumers do rely on said concealment and suppression.

160. Based on Defendant's concealment and suppression, Plaintiff did not know there were any age restrictions for Hello Rinse. Plaintiff therefore permitted his daughter to repeatedly use Hello Rinse long before she was 6 years old.

161. Plaintiff and the putative Illinois class members have suffered economic loss as a result of Defendant's violation of the ICFA.

162. Based on Defendant's concealment and suppression of the warnings and directions, Plaintiff and the Illinois Class members are entitled to relief under 815 ILCS §505/10a.

THIRD CAUSE OF ACTION
Deceptive Business Practices in Violation of
Other Similar State Statutes Identified Herein

163. Plaintiff incorporates the preceding paragraphs as if fully written herein.

164. Plaintiff brings this claim on behalf of the Arizona, California, Connecticut, Florida, Hawaii, Idaho, Minnesota, Missouri, New Jersey, New York, Virginia, Washington State, and Washington D.C. members of the proposed Class.

165. As described above, including but not limited to paragraph 109, Defendant's labeling of the Hello Rinse falsely, misleadingly, and deceptively conveys the impression that this product is specially formulated to be safe for young children.

166. Through this deceptive conduct, which violated, and continues to violate, the ICFA (815 ILCS 505/2), Defendant has simultaneously violated, and continues to violate, the following state consumer protection statutes:

- a. Arizona (A.R.S. § 44-1521, *et seq.*);

- b. California (Cal. Bus. & Prof. Code §17200, *et seq.* & Cal. Civ. Code § 1750, *et seq.*);
- c. Connecticut (Conn. Gen. Stat. § 42-110a, *et seq.*);
- d. Florida (Fla. Stat. § 501.201, *et seq.*);
- e. Hawaii (HRS § 481A-1, *et seq.*);
- f. Idaho (Idaho Code § 48-601, *et seq.*);
- g. Minnesota (Minn. Stat. § 325F.68, *et seq.*);
- h. Missouri (Mo. Rev. Stat. § 407.005, *et seq.*);
- i. New Jersey (N.J.S.A. § 56:8-1, *et seq.*);
- j. New York (NY GBL §§ 349-50);
- k. Virginia (Va. Code Ann. § 59.1-196, *et seq.*);
- l. Washington (Wash. Rev. Code § 19.86.010, *et seq.*);
- m. Washington D.C. (D.C. Code § 28-3904, *et seq.*).

167. Plaintiff and Class Members purchased Hello Rinse for their preschool children based on their reasonable reliance on Defendant's false, misleading, and deceptive labeling.

168. Plaintiff and Class Members suffered economic harm as a proximate result of Defendant's violations of these statutes by purchasing products they never would have purchased absent the deceptive practices given FDA's contraindication and the unacceptable risk the product poses to young children.

169. Alternatively, to the extent Hello Rinse is considered to have value for children six under six despite its contraindication and unacceptable risk profile, Plaintiff and Class Members were harmed by purchasing a product whose true value, absent the deceptive conduct, was far less than what they paid.

170. Through its deceptive and misleading acts and practices, Defendant has been unjustly enriched, and continues to be unjustly enriched, by unfairly obtaining money from members of the Class.

171. Based on Defendant's deceptive acts or practices, Plaintiff and the Class members are entitled to relief under the aforementioned state statutes.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and those similarly situated, respectfully request that the Court enter judgment against Defendant as follows:

- A. Certification of the proposed Class, including appointment of Plaintiff's counsel as Class counsel and Plaintiff as Class Representative;
- B. An award of compensatory damages in an amount to be determined at trial;
- C. An award of restitution in an amount to be determined at trial;
- D. An award of disgorgement in an amount to be determined at trial, except as to those causes of action where statutory damages are not available by law;
- E. An award of statutory damages in an amount to be determined at trial, except as to those causes of action where statutory damages are not available by law;
- F. An award of treble damages, except as to those causes of action where treble damages are not available by law;
- G. An award of punitive damages in an amount to be determined at trial, except as to those causes of action where punitive damages are not available by law;
- H. An order requiring Defendant to pay both pre- and post-judgment interest on any amounts awarded;
- I. For reasonable attorneys' fees and the costs of suit incurred; and

J. For such further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury on all Counts and as to all issues.

Dated: June 4, 2025

Respectfully Submitted,

By: /s/ Michael Connett

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